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10/009,235

06/11/2002

Jaak Decuypere

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HOWREY LLP

C/O IP DOCKETING DEPARTMENT

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FALLS CHURCH, VA 22042-7195

EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/009,235

Applicant(s)

DECUYPERE ET AL.

Examiner

Irene Marx

Art Unit

1651

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 9-12, 21 and 26-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9-12, 21 and 26-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed 4/13/06 is acknowledged.

Claims 1-3, 9-12, 21 and 26-32 are being considered on the merits.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is vague and indefinite in that "enzyme is present in a commercially available lipolytic enzyme composition" does not define the enzyme with any particularity.

Claims 28 and 29 are vague indefinite and confusing in the recitation of "synthetic" animal feed in claim 28. Generally "synthetic" is used with respect to man-made, such as fibers, for example. It appears incorrect to state that any of "starch, dextrose, casein" as recited in claim 29 are in fact, synthetic. Whether or not at least some of "a vitamin-mineral premix" are or are not synthetic is unclear.

Claims 29 and 31 are vague and indefinite in the recitation of "based on". It is unclear what is intended by this language. The modifications intended on the feed are not stated with any particularity. Thus the composition of the feed cannot be readily assessed.

Claim 30 is vague and indefinite in the recitation of "commercial" with respect to the feed. This designation does not define a feed with any particularity.

Claim 32 is vague, indefinite and confusing that there is no clear indication as to the nature of the materials in the prior art that wish to be excluded by the recitation of "consisting essentially of" particularly in the context of a composition using the open language "comprising", which does not limit the composition to the components specifically recited.

Thus, the claim as written are at least ambiguous as to what is intended.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel

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characteristic(s)" of the claimed invention. In re Herz , 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also Atlas Powder Co. v. E.I. duPont de Nemours & Co. , 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama - Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. v. Calco, Ltd ., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would

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have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 9-12, 21, 26-27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Melichar *et al.* or Nars or Salle *et al.* as evidenced by Tang *et al.*, and Hurley for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a feed composition, which is dry, comprising about 0.25 to about 10% triglyceride and about 100 to about 10,000 ppm lipolytic enzyme wherein the triglyceride contains C<sub>4</sub> to C<sub>12</sub> fatty acids.

Compositions comprising dry breast milk in lyophilized form are disclosed by Melichar *et al.* (See, e.g., Abstract) or Nars (See, e.g., Abstract) or Salle *et al.* (See, e.g., page 761, col. 2, paragraph 2) or Suranyi *et al.* (See, e.g., Abstract). It is well recognized in the art that lyophilized lipolytic enzymes retain activity. Enzymes, such as lipolytic enzymes are routinely lyophilized for storage. Breast milk is a complete food which constitutes an "animal feed" composition, since humans are animals.

Breast milk contains about 4% triglycerides as evidenced by Hurley and naturally contains about 100 ppm (0.1 mg/ml) of active bile-salt activated lipase among the lipases in the composition. Inasmuch as the claims as written are directed to a composition comprising triglycerides which contains or consists essentially of certain fatty acids, the nature of other triglycerides and/or fatty acids that are in the nutritional composition cannot be readily ascertained. The nature of other triglycerides and/or fatty acids comprised by the nutritional composition is not set forth with any particularity. Therefore, the breast milk from humans and other mammals appears to anticipate the claimed composition.

#### **Response to Arguments**

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

To begin with, contrary to applicant's contention, dried breast milk does, in fact, constitute a feed composition comprising certain triglycerides and lipolytic enzyme. Inasmuch as humans are animals, no distinction is seen.

Claims 1-3, 9-12, 21 and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hull *et al.* taken with Haas *et al.* and Tang *et al.*

Each of the Hull and Haas references discloses a composition suitable as a feed comprising medium chain fatty acids and one or more lipolytic enzymes. See, e.g., col. 2, lines 23-61 and Example, III, Table II, respectively. It is noted that at least Haas intends the composition to be dried. See, e.g., Example II. The composition disclosed contains at least starch, dextrose, and vitamins and minerals. Even if casein is not present, other proteins, from soy for example are provided. Whether the animals feed is from a commercial source or not does not affect the properties thereof. In addition, one of ordinary skill in this art would have recognize the desirability of optimizing the materials on which the feed is based by altering the feed depending on the subject intended to be fed therewith.

The references differ from the claimed invention in that the enzymes are not necessarily “active”. However, Tang *et al.* disclose the benefits of providing an active lipolytic enzyme such as bile-salt activated lipase in a feed composition for animals (See, e.g., Table III). The material is provided in conjunction with milk in Tang *et al.* but could also be provided in conjunction with the feed composition disclosed by Haas and discussed *supra.* One of ordinary skill in the art would have had a reasonable expectation of success of providing the same benefits of an active enzyme in any other dry feed composition containing triglycerides containing medium chain fatty acids, including the enzyme esterase, in view of the benefits of providing medium chain fatty acids *in situ*.

The intended methods of using the same feed compositions as a medicament, an antimicrobial and to prevent digestive upsets does not change the composition itself, which is taught by the references. Its properties are the same regardless of the intent.

Furthermore, the composition is claimed as a product-by-process with respect to “synthetic” and “commercial”. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the medium chain fatty acid containing compositions of Hull *et al.* and Haas *et al.* by providing active lipolytic enzymes as suggested by the teachings of Tang *et al.* for the expected benefit of providing free medium chain fatty acids *in situ* by degrading the triglycerides provided, which medium chain fatty acids have well recognized antimicrobial and digestive properties.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### **Response to Arguments**

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that Hull does not “contain an animal feed”. However, the broadest reasonable interpretation of an “animal feed” is any food for humans or animals, inasmuch as humans are animals. In addition, any “human” food can be provided to an animal to then constitute or become an animal feed, including buttermilk as taught by Hull. No patentable distinction is seen in the present context. It is noted also that indigent humans have been known to eat at least cat or dog food.

With respect to the dried aspect, it is noted that Haas *et al.* disclose a food or feed composition for animals that is dried.

The touted advantages of the invention are noted. However, there is no clear correlation between the advantageous properties touted and the invention as claimed. The Examples in the instant specification are directed to specific products. However, the claims are not directed with any particularity to these products.

There is no clear correlation between the arguments and the claim designated invention. Applicant appears to misinterpret the principle that claims are interpreted in the light of the specification. In this case, the elements of “industrially prepared triglycerides” in certain ratios are not clearly and explicitly found as examples or embodiments in the specification. In this case, also, the specific ratios are not claimed explicitly. Nor were the words that are used in the claims defined in the specification to require these limitations. A reading of the specification provides no evidence to indicate that these limitations must be imported into the claims to give

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meaning to disputed terms. The claims as written are directed to a composition comprising industrially prepared triglycerides which consist essentially of certain fatty acids. The claims do not clearly indicate the nature of other triglycerides and/or fatty acids that are in the nutritional composition.

Moreover, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In *re Herz*, 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In *re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or component would materially change the characteristics of applicant's invention. In *re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").



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As noted *supra*, in the instant case, there is no clear indication as to the materials in the prior art that wish to be excluded by the recitation of "consisting essentially of" particularly in the context of a composition using the open language "comprising", which does not limit the composition to the components specifically recited. Thus, the claims as written are at least ambiguous as to what is or is not included or excluded from the feed composition.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' composition differs and, if so, to what extent, from the compositions produced by humans and other mammals. Therefore, the burden of establishing non-obviousness by objective evidence shifted to Applicants. Applicants have not met that burden.

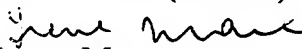
The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Irene Marx  
Primary Examiner  
Art Unit 1651